ANDA 75-272/S-003, S-004 March 1, 2002

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your supplemental new drug applications dated September 14, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), regarding your abbreviated new drug application for Buspirone Hydrochloride Tablets USP, 5 mg, 10 mg, and 15 mg.

Reference is also made to the Tentative Approval letters issued on November 10, 1998, August 2, 2000, and March 28, 2001.

Reference is also made to your amendment dated February 19, 2002.

These supplemental applications provide for the final approval of the 5 mg and 10 mg strengths and the following changes:

S-003: Labeling

S-004: Control Revision

The listed drug product (RLD) referenced in your supplemental applications, BuSpar® Tablets of Bristol Myers Squibb Co. Pharmaceutical Research Institute (BMS), is subject to a period of patent protection which expires on November 14, 2008 (U.S. Patent No. 5,015,646 [the ‘646 patent]). Your application contains a Paragraph IV Certification to the ‘646 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on this patent or that the patent is otherwise invalid. You have further notified the Agency that Mylan Pharmaceuticals Inc. (Mylan) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no legal action regarding the ‘646 patent was brought against Mylan within the statutory forty-five day period.

Furthermore, the Act provides that approval of an abbreviated application that contains a certification described in Section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), and that is for a drug product for which a previous abbreviated application has been submitted which also contains a Paragraph IV Certification, shall be made effective not earlier than one hundred and eighty days after:

1. the date the Secretary receives notice of the first commercial marketing of the drug product under the previous application, or

2. the date of a final decision of a court holding the patent(s) which is the subject of the certification to be invalid or not infringed, whichever event occurs first {Section 505(j)(5)(B)(iv)}.

As noted in the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), an abbreviated new drug application for Buspirone 5 mg and 10 mg was approved for Danbury Pharmacal, Inc. (Danbury) on March 28, 2001. This application also contained a Paragraph IV Certification and was the first application received by the Agency for this drug product. Consequently, Danbury became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", Danbury's market exclusivity expired on September 26, 2001.

We have completed the review of these supplemental abbreviated applications and have concluded that the 5 mg and 10 mg strengths of the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The Division of Bioequivalence has determined your Buspirone Hydrochloride Tablets USP, 5 mg and 10 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (BuSpar® Tablets, 5 mg and 10 mg, respectively, of BMS). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We remind you that you must comply with the requirements for an approved abbreviated application described in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research